

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

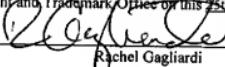
Applicant: Gene DIPOTO et al. Confirmation No.: 9623  
Serial No.: 10/693,663 Examiner: James L. Swiger, III  
Filed: October 24, 2003 Group Art Unit: 3733  
Docket No.: 1291.1142101 Customer No.: 28075  
Title: METHODS AND APPARATUSES FOR FIXATION OF THE SPINE  
THROUGH AN ACCESS DEVICE

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MAIL STOP: AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 25th day of March, 2009.

By   
Rachel Gagliardi

Applicant submits that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection. All rejections in the current Office Action are repeated exactly from the previous Office Action, however in response to Applicant's detailed arguments presented Nov. 4, 2008, the Examiner merely states, "Applicant's arguments filed 11/4/2008 have been fully considered but they are not considered persuasive." See page 5 of the Office Action. The Examiner provides no comments or answers to the Applicant arguments. This is an error.

MPEP 707.07(f) Answer All Material Traversed [R-3]

Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.

Applicant notes that the second Examiner Note after the suggested Form paragraph 7.37 Arguments Are Not Persuasive section of MPEP 707.07(f), the MPEP specifically states,

"provide explanation as to non-persuasiveness." The Examiner's repetition of all rejections without answering the substance of the traversal presented in the prior response is an error.

Claims 1-4, 6-12, 14-18, and 23-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cornwall et al. (U.S. Patent No. 6,485,518) in view of Davison (U.S. Patent No. 6,530,926). The Examiner asserts that Cornwall et al. teach the step of positioning a cannula at a preferred angle to perform a percutaneous procedure, and asserts that this is considered inclinining. Applicants respectfully disagree. One of ordinary skill in the art would not consider the step of placing a cannula into the body at a preferred angle as a positive method step of "after said inserting step, inclining said access device from a plane that is generally perpendicular to the spine of the patient" as recited in claims 1 and 14. MPEP 2111 states:

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

...

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)

Applicants submit that one of ordinary skill in the art, upon reading the specification, would not interpret the claims as reciting merely positioning a cannula at a fixed angle. In particular, the claims specifically state a temporal relationship between two steps. The inclining step is after the inserting step, indicating two actions are performed: (1) inserting an access device, and then (2) inclining the access device. Cornwall et al. do not appear to teach or suggest such specific steps. Further, the Examiner's assertion that the positioning step of Cornwall et

al. meets the inserting and inclining steps appears to be an acknowledgement that Cornwall et al. do not teach a separate inclining step.

The Examiner also asserts that “the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws.” The Examiner provides no support in the reference itself for this statement. It appears the Examiner may be considering the movement of the surgeon in removing one cannula after insertion of a first screw, and moving the cannula to the other side of the patient’s spine for insertion of the second screw, as somehow meeting the claimed step of “inclining”. Cornwall et al. provides no such teaching or suggestion. As discussed above, the claims recite temporally separate inserting and inclining steps, while Cornwall et al. appear to teach a single step of inserting a cannula at a desired, fixed angle. Whether Cornwall et al. may teach inserting a cannula at an angle that crosses a midline appears to be irrelevant with regard to any teaching of a specific method step of inclining an access device after the access device is inserted to a desired location.

The Examiner appears to assert, on page 3 of the Office Action, that Davison teaches the step “of the device moving from a plane generally perpendicular to the spine of the patient at an established angle”, but does not provide any support for the assertion. The Examiner then asserts that the cannula may be slightly angled to complete the procedure and deliver the screws. The Examiner provides no support for this assertion. Neither Cornwall et al. nor Davison appear to teach such specific steps. The Examiner appears to be asserting that the claimed method steps are inherent in Cornwall et al. and/or Davison, or that one could perform the claimed method using the devices of Cornwall et al. and/or Davison. The Examiner is reminded that MPEP 2112 IV. states that inherency requires a feature to be necessarily present. There is no teaching or suggestion that the specifically recited method steps are necessarily present in either Cornwall et al. or Davison. Additionally, the Examiner has failed to provide any reasoned statements of motivation for performing the specific method steps recited in the claims. The Examiner provides no support for the mere conclusion of obviousness. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless \*\*>the results would have been

predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)

Applicant submits that modifying Cornwall to achieve the specific claimed method steps, in addition to not being obvious, would not have been predictable to one of ordinary skill in the art.

Additionally, Cornwall appears to teach a preferred method and system involving inserting 2 facet screws, where each screw is inserted through a separate narrow cannula at a specific angle through two vertebra. As discussed in the response filed February 20, 2007, at page 10, third paragraph, it would appear that if an enlarged/expandable elongate body, as discussed in Davidson, were used in the method disclosed in Cornwall, it would defeat the purpose of Cornwall's specifically oriented guideframes that orient narrow cannulae to deliver narrow implants to specific locations at specific orientations. In other words, Cornwall thus appears to teach away from replacing their narrow cannula in the facet screw placement procedure with the enlarged/expandable elongate body of Davidson. For at least the reasons set forth above, the rejection is in error and should be withdrawn.

Claims 5 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cornwall et al. (U.S. Patent No. 6,485,518) and Davison (U.S. Patent No. 6,530,926) as applied to claims 1 and 8, respectively above, and further in view of Neubardt (U.S. Patent No. 5,196,015). This rejection is respectfully traversed. As discussed above, there is no motivation for one of ordinary skill in the art to combine Davison and Cornwall, and even if such a combination were made, the elements of independent claim 1, from which claims 5 and 13 depend, are not taught or suggested. Naubardt does not appear to provide what Davison and Cornwall lack. Naubardt does not appear to provide any motivation or suggestion for modifying Davison and/or Cornwall to achieve the method steps recited in independent claim 1, or dependent claims 5 and 13. This rejection is thus in error and should be withdrawn.

Claims 19-20 and 21-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Cornwall et al. (U.S. Patent No. 6,485,518) and Davison (U.S. Patent No. 6,530,926). This rejection is respectfully traversed. For at least the reasons set forth above, Cornwall et al. and Davison do not appear to teach or suggest the elements of independent claims 1 and 14, from which claims 19-20, and 21-22 depend, respectively.

There is no motivation for one of ordinary skill in the art to further modify Cornwall et al. and/or Davison to achieve the specific method steps recited in claims 19-22. This rejection is thus in error and should be withdrawn.

**CONCLUSION**

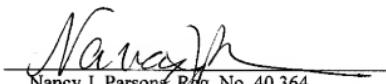
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gene DIPOTO et al.

By their attorney,

Date: 3/25/09



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